

IN THE SPECIFICATION

Please replace paragraphs [0012], [0013], and [0027]:

[0012] An exemplary method of delivering radiation therapy according to the present invention includes a balloon catheter that is inserted into a tumor resection cavity created by the surgical removal of a tumor. Fig. 1 shows an exemplary apparatus used to place the balloon catheter at a selected location, e.g., in the breast tissue. For example, the apparatus may include a MammoSite® RTS radiation therapy balloon produced by Proxima Therapeutics, Inc. As shown in Fig. 1, a balloon 12 is placed within the cavity 10 that is left in tissue 20 after a tumor has been surgically removed and the cavity 10 has been subjected to any post-lumpectomy treatment. The balloon 12 is placed via a catheter 14 which may be inserted to the resection cavity 10 through a trocar 22 from outside the patient's body through the incision made when the tumor was removed, or through a separate incision made with a scalpel at a later time. The balloon 12 is inserted into the resection cavity 10 in a deflated state and, once properly positioned is inflated using, for example, a saline solution and contrast media, to uniformly contact the tissue of the cavity so that the surrounding tissues and the inflated balloon 12 conform to one another.

[0013] The therapeutic effect of the radiation therapy balloon 12 is obtained by inserting therinto a radioactive seed 18. For example, the seed 18 may be an Ir¹⁹² radioactive source. The seed 18 is connected by a wire to an afterloader 16, which is a computer controlled device that determines the exact location at which the seed 18 is to be placed within the balloon 12 and the length of time of the exposure, so that the appropriate amount of radiation is delivered to the targeted tissue. The afterloader 16 may be, for example, one of the devices manufactured by Nucletron, Varian and GammaMed HDR. As would be understood by those of skill in the art, the position of the seed 18 within the balloon 12 may be maintained by inserting a rod into the seed lumen. After the therapeutic session has been completed, the seed 18 is removed so that there is no source of radiation left in the patient's body between treatments. The balloon 12, however, may typically remain inflated within the cavity 10 between radiation sessions throughout the duration of the course of treatment. After the course of treatment has been completed, the balloon 12 is deflated and is removed together with catheter 14. The radiation therapy delivered with the balloon catheter may be used alone, or may provide a very targeted boost to other types of therapy, such as external beam radiation therapy and/or chemotherapy.

[0027] When sufficiently recovered to resume treatment, the patient returns to a medical

facility, preferably on an outpatient basis. Depending on the specific design of the pretreatment balloon 40, radiation therapy treatment may be carried out using the pretreatment balloon 40 itself as a container for a radioactive seed 18, as described above. That is, after a predetermined healing time has elapsed, a radioactive seed 18 may be inserted therein to begin radiation therapy. If there is no time lapse between the surgery and the initiation of the radiation treatment, the tissue spacing function of the balloon is not needed for the initial placement of the radioactive seed 18. Alternatively, after the pretreatment balloon 40 has been used to prevent premature healing by separating the surrounding tissue, it may be removed and a different radiation therapy balloon may be placed in the resection cavity to receive the radioactive seed 18. In cases where the pretreatment balloon 40 remains in use to carry out radiation therapy, a radioactive seed 18 attached to an external afterloader with a wire is inserted through a port 32 and is placed at a desired location (e.g., under computer control) within the balloon 40 so that the seed 18 resides at a desired position within the resection cavity. When the appropriate dose of radiation has been administered, the radioactive seed 18 is removed. If, after a particular application, the course of treatment has not yet been completed, the pretreatment balloon 40 is left inflated in the cavity, to prevent its closing until the next treatment session. Otherwise, the balloon 40 may be removed to allow the resection cavity to heal.